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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/866,927

05/30/2001

Robert H. Getzenberg

076333-0240

6351

22428

7590

03/10/2004

FOLEY AND LARDNER

SUITE 500

3000 K STREET NW

WASHINGTON, DC 20007

EXAMINER

HELMS, LARRY RONALD

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/866,927

Applicant(s)

GETZENBERG, ROBERT H.

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,8-11 and 13-24 is/are pending in the application.
- 4a) Of the above claim(s) 2-6,8,9 and 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,10,11 and 19-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Request for Continued Examination***

1. The request filed on 12/23/03 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/866,927 is acceptable and a RCE has been established. Claims 1-6, 8-11, 13-24 are pending and claims 1, 10-11, 19-24 are currently under prosecution. An action on the RCE follows.
2. Claims 2-6, 8-9, 13-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made in Paper No. 8.
3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

### ***Response to Arguments***

4. The rejection of claims 1, 10-11, 19-24 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

The response filed 12/23/03 has been carefully considered but is deemed not to be persuasive. The response states that applicant has supplied a new photograph of a 2-D gel showing the molecular weight of BLCA-6 of 31 kD which is above the 29-kDa

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marker and the Declaration of Getzenberg is evidenced of the apparent error in molecular weight and the response submits a preprint of the article of Getzenberg et al in Cancer Research and state that the MW of the BLCA-6 protein is 31-kD and a pl of 8.0. In response to this argument, the Declaration and response has been carefully considered but is deemed no to be persuasive. The support for the 31-kD protein only comes from evidence not in the specification as originally filed. The specification does not have any 2-D gel or labeled protein on the gel that indicates that BLCA-6 should be 31-kD. The only evidence in the specification is that BLCA-6 is 22-kD found in Table 1. The specification contains only two figures which do not indicate the MW of any of the BLCA proteins. Without the 2-D gels one skill in the art would not know that the BLCA-6 protein is 31-kD or supposed to be 31-kD. Although the response states that this is an inherent property of the protein, without the gels one can not know what the MW is suppose to be except 22-kD.

5. The rejection of claims 1, 10-11, 19-24 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

The response filed 12/23/03 has been carefully considered and is deemed not to be persuasive. The response states that it is an inherent property of the BLCA-6 protein having SEQ ID NO:4 and has a MW of 31-kD and pl of 8.0 (see page 8 of response). In

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response to this argument, There is no indication in the specification as originally filed to indicate that BLCA-6 is 31-kD. Although SEQ ID NO:4 is associated with the 22-kD protein, BLCA-6 in the specification, there is no evidence that the 31-kD protein has SEQ ID NO:4. In addition, even if the 31-kD protein has SEQ ID NO:4, this does not give evidence that the 22-kD protein should be BLCA-6 because the 31-kD protein that has SEQ ID NO:4 could also be processed to a 22-kD protein in the specification that has SEQ ID NO:4. Therefore, one skill in the art would not be able to make and use the invention because the specification does not teach a 31 kDa protein. In addition a person reading the specification would only conclude that BLCA-6 is 22 kDa and a pl of 8 and comprise a sequence of SEQ ID NO:4. With these three facts a skilled artisan would not be able to make the claimed invention. Although there is an indication (in the prior art and the declaration of Getzenberg) that the molecular weight is incorrect, there is nothing from the specification as filed to indicate that this is true. One could also equally argue that the pl or the sequence is incorrect.

Thus, the specification does not describe the invention to enable one skill in the art to make and use the invention.

### ***Priority***

6. Due to the new matter and enablement rejections above the claims in the instant application are granted the priority date of the instant application, 5/30/2001.

***Claim Rejections - 35 USC § 102***

7. The rejection of claims 1, 10-11, 20, 24 under 35 U.S.C. 102(b) as anticipated by Getzenberg et al (Cancer Research 56:1690-4, 1996) is maintained.

The response filed 12/23/03 has been carefully considered but is deemed not to be persuasive. The response states that the priority date of the application is 11/95 and as such the reference of Getzenberg et al is not a patent defeating reference. In response to this argument, the priority date of 5/01 stands because of the new matter rejection above. As such the rejection is maintained.

8. The rejection of claims 1, 10-11, 19-24 under 35 U.S.C. 103(a) as being unpatentable over Getzenberg et al (Cancer Research 56:1690, 1994) as applied to claims 1, 10-11, 20, and 24, and further in view of Coffey et al (U.S. Patent 6,030,793, priority to 2/93) is maintained.

The response filed 12/23/03 has been carefully considered but is deemed not to be persuasive. The response states that the priority date of the application is 11/95 and as such the reference of Getzenberg et al is not a patent defeating reference. In response to this argument, the priority date of 5/01 stands because of the new matter rejection above. As such the rejection is maintained.

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**Conclusion**

9. No claim is allowed.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER